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To: Division of Dockets Management (HFA-305)
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From: Nava Rotem Ph. D.
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Re: Docket No. 2005D-0288

Comments to International Conference on harmonization; Draft Guidance on Q9 Quality Risk Management

Teva API division has reviewed the above draft guidance and our comments are listed below:

1. The guidance document should clarify the authorities' expectations when the risk assessment should be used and what is the outcome of this process. Should these documents be submitted to authorities (What? When? How?), or have it in place and presented during inspection if required?
2. The guideline should clarify what are the regulatory benefits of risk assessment protocols submitted to the authorities for review. For example: If the submission file includes a protocol for site transfer will it reduce the variation level when such change is implemented? Similarly, if the submission file includes risk assessment of reduced testing will it be acceptable to reduce tests without submitting a variation?
3. We suggest to add examples of use of the various statistical tools included in the guideline. Also to add more clarifications when it is appropriate to use each of these methods.

Regards,

Nava Rotem

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